REMARKS

Reexamination and reconsideration of this application is respectfully requested in light of the foregoing amendments to claims 1 and 5 and the following remarks.

Claims 1 and 3-7 are pending in this application. Claim 2 was canceled in a previous amendment. Claims 1 and 5 have been amended in response to the new rejection under 35 U.S.C. § 112, second paragraph, *infra*. No new claims are presented for examination.

Applicant notes that the previous response filed November 24, 2008 overcame the claim objections, double patenting rejection of the claims, the rejection of claim 5 under 35 U.S.C. § 112, and the rejection of claims 1, 3, 6 and 7 over Goldberg et al. (U.S. Patent No: 4,819,617). Applicant further notes the Examiner's approval and entry of the Terminal Disclaimer filed on March 27, 2007.

Rejections Under 35 U.S.C. § 112

Claims 1, 6 and 7 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. According to the Office Action, the claims contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed subject matter at the time the application was filed. Specifically, the Office Action maintains that the terms "polysaccharides or polypeptides" are so broad as to encompass a myriad of possibilities. Applicant respectfully disagrees.

The specification beginning at page 17, line 7 states that "virtually any biocompatible, water-soluble polymer (e.g., polysaccharides, polypeptides, carbohydrates, a synthetic polymers and their salts) having a molecular weight > 50,000 D and concentration to provide sufficient viscosity to protect tissue services may be used to produce the tissue-protective aqueous solutions of the present invention ...." This disclosure would reasonably convey to a person

skill in the art that the inventors had in their possession an understanding that any polysaccharide or polypeptide is usable. The claimed subject matter further requires that the polymer does not contain hyaluronic acid having a molecular weight above about 1,500,000 and chondroitin sulfate, salt, complex or a mixture thereof. These components have no relevance to the chemical structures for the polysaccharides or polypeptides that are usable. Therefore, the inventors had in their possession the concept that any polysaccharide or polypeptide can be used. For these reasons, it is respectfully requested that this rejection be reconsidered and withdrawn.

Claims 1 and 3-7 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because the combined use of the terms "above about" in claims 1 and 5 to define the molecular weight of the hyaluronic acid renders the scope of the claims indefinite. The claims have been amended to recite that the molecular weight is "about 1,500,000 and above." Support for the amendment can be found in the specification at page 11, lines 20-21 and page 19, line 7 to page 20, line 13. In view of the amendments to the claims, it is believed that the rejection is overcome. Accordingly, it is respectfully requested that this rejection be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 103

Claims 1, 3, 6 and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lambert (U.S. Patent No. 4,585,666) in view of Schwartz et al. (U.S. Patent No. 4,589,873). The references taken alone or in combination fail to teach the claimed subject matter.

Claim 1 is directed to a method of protecting tissue and reducing tissue damage in surgery. The method recites coating surfaces involved in surgery (tissue and/or instruments) with a physiologically acceptable aqueous solution of a hydrophilic, polymeric material prior

to manipulation of said tissue during said surgery. Claim 1 further requires that the polymeric material exclude (i) hyaluronic acid having a molecular weight about 1,500,000 and above, and (ii) chondroitin sulfate, salt, complex or mixture thereof. The Office Action does not address this limitation or show where this limitation is disclosed or suggested in either Lambert or Schwartz et al. The Office Action fails to present any cogent scientific reasoning from the teachings of the references that this limitation would have led a person skilled in the art to the claimed invention.

In addition to the above, claim 1 further requires that the concentration of the polymer in the aqueous solution be in the range of from about 0.01% to about 15% by weight and that the molecular weight of the polymer and the concentration have values such that the aqueous solution is capable of providing wet coatings on said surfaces involved in surgery. The Office Action fails to show, by cogent reasoning, how the combined teachings of Lambert and Schwartz et al. would have lead a person skilled in the art to arrive at the claimed concentration range to achieve a wet coating.

For the foregoing reasons, the Office Action fails to present a *prima facie* case of obviousness over the combined teachings of Lambert or Schwartz et al. Since claims 3, 6 and 7 further limit claim 1 to the embodiments contained in claim 1, a *prima facie* case has not been established with respect to these dependent claims for the same reasons. Accordingly, it is respectfully requested that the rejection of claims 1, 3, 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Lambert and Schwartz et al. be reconsidered and withdrawn.

Claims 1, 3, 6 and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Schacher (U.S. Patent No. 4,510,145) in view of Chiou (U.S. Patent No. 4,565,821).[1] Claim 1 requires that the polymeric material exclude (i) hyaluronic acid having a molecular

[1] In the Office Action, the patent number for Chiou was incorrectly reported as U.S. Patent No. 4,564,821.

weight about 1,500,000 and above, and (ii) chondroitin sulfate, salt, complex or mixture thereof. The Office Action does not address this limitation or show where this limitation is disclosed or suggested by Schechter and Chiou, either taken alone or in combination. The Office Action fails to present any cogent scientific reasoning from the combined teachings of the references that this limitation would have been within the skill of the art.

In addition to the above, claim 1 further requires that the concentration of the polymer in the aqueous solution be in the range of from about 0.01% to about 15% by weight and that the molecular weight of the polymer and the concentration have values such that the aqueous solution is capable of providing wet coatings on said surfaces involved in surgery. While Schacher does disclose using a carboxymethylcellulose as a building agent to control viscosity in an ophthalmic, there is no disclosure or suggestion from the teachings of Schacher that (i) the carboxymethylcellulose has a molecular weight of about 50,000 D or above and (ii) the concentration range of 0.001% to about 1.0% in the solution as disclosed in Schacher combined with the molecular weight of carboxymethylcellulose provides a wet coating on the surfaces involved in surgery. Further, it is not clear from the teaching of the reference that the solution is an aqueous solution since non-aqueous solutions are disclosed at col. 2, lines 31-39.

Chiou does not make up for the deficiencies of Schacher. While, Chiou does disclose using carboxymethylcellulose having molecular weights of from 10,000 to 1,000,000, there is no teaching or suggestion in the reference that a carboxymethylcellulose having such a molecular weight in the concentration ranges disclosed in Schacher would have led a person skilled in the art to the claimed subject matter, i.e., to provide a wet coating on the surfaces involved in surgery. Moreover, the carboxymethycellulose suggested by Chiou is not in a solution, but is described as a solid medicament (col. 6, line 58 to col. 7, line 28).

Accordingly, the references are not combinable and would not have led a person skilled in the art to the claimed invention.

For the foregoing reasons, the Office Action fails to present a *prima facie* case of obviousness over the combined teachings of Schacher and Chiou. Since claims 3, 6 and 7 further limit claim 1 to the embodiments contained in claim 1, a *prima facie* case has not been established with respect to these dependent claims for the same reasons. Accordingly, it is respectfully requested that the rejection of claims 1, 3, 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Schacher and Chiou be reconsidered and withdrawn.

Claims 1 and 5-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Soll et al. (U.S. Patent No. 4,486,416) as evidenced by Gough (U.S. Patent No. 4,335,105). Tables 2 and 3 of Soll et al. are relied upon in the Office Action to show a solution containing a polypeptide (bovine serum albumin), hyaluronic acid, polyvinylpyrrolidone and chrondroitin sulfate. Despite this finding, the Examiner concedes that Soll et al. "does not explicitly teach utilizing the polyvinylpyrrolidone, bovine serum albumin, or hyaluronic acid in the claimed method." Applicant agrees, but further finds that Soll et al. require chrondroitin sulfate and teach away from the claimed invention.

The wet coating as recited in claim 1 excludes (i) hyaluronic acid having a molecular weight about 1,500,000 and above, and (ii) chondroitin sulfate, salt, complex or mixture thereof. The Office Action relies on a teaching at col. 4, lines. 37-40 of Soll et al. as teaching that sodium hyaluronate polymer has having a molecular weight of 1,000,000. While this teaching may establish that Soll et al. disclose a hyaluronic acid that meets the claim limitation, the wet coating of the claim excludes chondroitin sulfate, a key ingredient in Soll's composition.

The compositions in Tables 2 and 3 are relied on in the Office Action as disclosing or suggesting the claimed subject matter. However, without chondroitin sulfate in the composition, a person skilled in the art would not have been led to conclude that a composition without chondroitin sulfate would protect tissue and reduce tissue damage.

In Table 2, the results of a composition comprising chondroitin sulfate, bovine serium albumin, and polyvinyl pyrrolidone show that with chondroitin sulfate present, 2-5% of corneas tested were damaged. However, the same composition without chondroitin sulfate, showed a significantly higher number of cornea's damaged. A composition comprising only chondroitin sulfate and bovine serium albumin showed only 0-1% of the corneas were damaged. However, using bovine serium albumin alone, there was a higher percentage of damage. A composition comprising bovine serium albumin and hyaluronic acid showed similar results. Thus, without chondroitin sulfate in the composition, the percentage of corneas damaged significantly increases. The same results appear in Table 3.

These results would lead a person skilled in the art away from using a composition that did not contain chondroitin sulfate. Accordingly, the teaching of Soll et al. would not have lead such a person to expect Soll's compositions, without chondroitin sulfate, to protect tissue and reduce tissue damage as required by claim 1.

The teaching of Gough does not make up for the deficiencies of Soll et al. The reference appears to be only relied upon to show that bovine serum albumin is greater than 50,000 D. However, even if this is true, there is no teaching or suggestion in Gough that the compositions in Soll et al., without chondroitin sulfate, would be expected to protect tissue and reduce tissue damage.

For all of the foregoing reasons, the Office Action fails to present a *prima facie* case of obviousness in the rejection of claim 1 over the combined teachings of Soll et al. and

Gough. Since claims 3, 6 and 7 further limit claim 1 to the embodiments contained in claim 1, a *prima facie* case has not been established with respect to these dependent claims for the same reasons. Accordingly, it is respectfully requested that the rejection of claims 1, 3, 6 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Soll et al. and Gough be reconsidered and withdrawn.

Claims 4 and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Soll et al. as evidenced by Gough in view of Lambert. The arguments *supra* with respect to the deficiencies of Soll et al., Gough and Lambert references are incorporated herein by reference. For reasons already stated, none of these references disclose or suggest a composition excluding (i) hyaluronic acid having a molecular weight about 1,500,000 and above, and (ii) chondroitin sulfate, salt, complex or mixture thereof to produce an aqueous solution to provide an aqueous solution is capable of providing wet coatings on said surfaces involved in surgery.

The rejection does not present a *prima facie* case of obviousness. Accordingly, it is respectfully requested that the rejection of claims 4 and 7 under 35 U.S.C. § 103(a) as being unpatentable over Soll et al., Gough and Lambert be reconsidered and withdrawn.

Conclusion

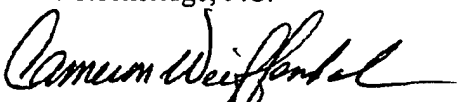
For the foregoing reasons, it is submitted that the claims 1 and 3-7 are patentable over the teachings of the prior art relied upon by the Examiner and satisfy the requirements of the first and second paragraphs of 35 U.S.C. § 112. Accordingly, favorable reconsideration of the claims is requested in light of the preceding amendments and remarks. Allowance of the claims is courteously solicited.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicant's attorney at the telephone number shown below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due under 37 C.F.R. § 1.17 and due in connection with the filing of this paper, including extension of time fees, to Deposit Account 501165 and please credit any excess fees to such deposit account.

Respectfully submitted,

Miles & Stockbridge, P.C.



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